

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

ENZO BIOCHEM, INC. and ENZO LIFE
SCIENCES, INC.,

Plaintiffs,

v.

03 Civ. 3817 (RJS)

PERKINELMER, INC. and PERKINELMER
LIFE SCIENCES, INC.,

Defendants.

**PERKINELMER'S OPPOSITION TO ENZO'S MOTION TO EXCLUDE CERTAIN
EXPERT TESTIMONY AND OPINIONS OF DR. LOUIS P. BERNEMAN**

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The Court should deny Enzo’s motion to preclude certain expert testimony by PerkinElmer’s expert, Dr. Louis P. Berneman, regarding the custom and usage of various terms in the Distributorship Agreement.

“Commercial” and “Research” Terms. With respect to Dr. Berneman’s opinions concerning the “commercial” and “research” terms, Enzo sets up and then attacks a straw man. Enzo argues that Dr. Berneman improperly interpreted “commercial use,” “commercial development,” and “commercial exploitation” because he treated these phrases synonymously. As Dr. Berneman repeatedly stated during his deposition, the three phrases are “related,” but not “synonymous” or “identical.” The phrases “commercial use,” “commercial development,” and “commercial exploitation” generally appear serially in the Agreement. As set forth in Dr. Berneman’s report and as confirmed during his deposition, the customary and industry meaning of those phrases would proscribe certain types of “commercial” activity but not “research” activity. Thus, Dr. Berneman’s opinion actually focuses on the word “commercial,” which appears in each of these three related phrases, without offering an opinion on any specific differences between “use,” “development,” and “exploitation.” Accordingly, Dr. Berneman’s analysis and conclusions do not violate any canon of contract interpretation.

Enzo also suggests that Dr. Berneman’s allegedly flawed opinion about the “commercial” terms necessarily requires preclusion of his opinion about the “research” terms. But Enzo offers no criticism of Dr. Berneman’s opinion on the meaning of “research” *per se*. Its effort to leverage its other objection into a basis for excluding Dr. Berneman’s opinion as to the meaning of the research terms makes no legal or logical sense.

“Covered By” Term. Enzo also seeks to preclude Dr. Berneman from offering an opinion relating to the term “covered by one or more claims” in the Distributorship Agreement.

This aspect of Enzo's motion is moot in view of the fact that PerkinElmer will not be offering Dr. Berneman's opinions at trial on that issue, given Enzo's concession that none of its own expert witnesses has offered an opinion on the issue. Accordingly, this aspect of Enzo's motion should be denied as moot.

ARGUMENT

I. DR. BERNEMAN'S OPINIONS ARE BASED ON DECADES OF EXPERIENCE AS WELL AS RELEVANT DOCUMENTS AND REGULATORY MATERIALS

Dr. Berneman has over thirty years of experience in licensing and "technology transfer"¹ in the life sciences industry. Ex. 1, Berneman Report at 1-3. He served as President of the Association of University Technology Managers ("AUTM") and Vice President and Trustee of the Licensing Executives Society U.S.A. & Canada ("LES"). *Id.* Previously, he was Managing Director of the Center for Technology Transfer ("CTT") and Intellectual Property Administrator ("IPA") at the University of Pennsylvania. *Id.* In that capacity, he was responsible for negotiating hundreds of options and licenses, including many related to tangible research materials (research tools), as well as collaboration and research and development agreements. *Id.* He has also served as Director of Licensing and Business Development at the Commonwealth of Virginia's Center for Innovative Technology ("CIT"). *Id.* In that role, Dr. Berneman worked with faculty and administrators at the eight public research universities in Virginia, including the University of Virginia and Virginia Tech, as well as with private companies, investors, and entrepreneurs to patent, license, and commercialize discoveries. *Id.* Dr. Berneman also has considerable experience in the private sector, including as the founder and executive of several biopharmaceutical ventures. *Id.* Dr. Berneman is currently Managing Director of Texelerate,

¹ "Technology transfer" is the evaluation, protection and commercialization of discoveries deriving from research and it involves, generally speaking, the transfer or exchange of technologies between academia and the private sector, between companies in the private sector, and/or between governments. Ex. 2, Berneman Dep. Tr. 65:11-70:7.

LLC, a technology transfer consulting firm focusing on start-up ventures, royalty monetization, and licensing transactions. *Id.*

Dr. Berneman was retained to offer expert opinions regarding, *inter alia*, the customary and industry understanding of certain terms in the Distributorship Agreement, in response to Enzo's contention that "applied research" is prohibited by the Agreement. *See Ex. 3, Azarani Report at 9.* The Distributorship Agreement provides, in relevant part:

except for DISTRIBUTION under the terms and conditions as set forth in this AGREEMENT, purchase by NEN or any of its research end-user customers does not include or carry any right or license to use, develop or exploit these PRODUCTS commercially, including any right to sell these PRODUCTS to other distributors who are not NEN Affiliates or NEN Distributors or NEN Representative Sales Agencies, and that any commercial use, development or exploitation of these PRODUCTS without the express written authorization of ENZO is strictly prohibited

Ex. 4, Distributorship Agreement, Paragraph 1(f) (emphasis added); *see also id.* at Paragraph 1(e).

Dr. Berneman offered his opinions with respect to the "commercial use, development, or exploitation" of research products in the life sciences industry. Ex. 1, Berneman Report at 3-4, 30-34. Based on his own experience and knowledge, the literature in the field, certain policy statements and guidelines from the National Institute of Health ("NIH"), the AUTM Technology Transfer Practice Manual, and a review of approximately fifty licensing and technology transfer agreements relating to the types of products subject to the Distribution Agreement, Dr. Berneman concluded, *inter alia*, that "[t]here is no basis or support in industry customary and standard practice to conclude that 'applied research' constitutes Commercial Use, Commercial Exploitation, or Commercial Development." *Id.* at 3-4, 30-34. In Dr. Berneman's view, the customary and industry meaning of "commercial use," "commercial development," and "commercial exploitation" would be "employing the product in an activity directly tied to

generating a commercial return (such as using the product for or in conjunction with a diagnostic test for which a customer would be charged a fee) or generating a commercial return by reselling the product.” *Id.* His opinions in that regard were further supported by the deposition testimony of certain party and nonparty witnesses. *See, e.g.,* Ex. 5, 2014-01-24 Dimond Dep. Tr. at 77:11–78:13 (A: “We would have interpreted, because of the sentence about any commercial use, development or exploitation . . . [as] related to people not being able to take the product and resell it as their own product or make another product out of it to sell it or use it to manufacture a product.”).

In addition, Dr. Berneman offered certain opinions relating to customary and industry usage and understanding of “research use,” “research purpose,” “research market,” or “research field” for research products in the life sciences industry. On the basis of his own experience and a wealth of materials, including research market reports and various regulatory guidelines, Dr. Berneman concluded that “[t]hose terms encompass both types of research,” *i.e.* “basic” and “applied” research. Ex. 1, Berneman Report at 3-4, 20-30.

II. THE COURT SHOULD DENY ENZO’S MOTION TO PRECLUDE TESTIMONY REGARDING THE “COMMERCIAL” AND “RESEARCH” TERMS.

Enzo does not dispute that expert testimony is admissible in cases involving contract interpretation to “describe[] industry practices and customs, define[] terms of art used in the industry, [and] explain[] the approach by which reasonably prudent [industry members] would interpret the contract documents.” *Iacobelli Constr., Inc. v. Cnty. of Monroe*, 32 F.3d 19, 25 (2d Cir. 1994); *see also Travelers Indem. Co. v. Scor Reinsurance Co.*, 62 F.3d 74, 78 (2d Cir. 1995) (expert testimony regarding “custom or practice” admissible for aiding jury in contract interpretation). Instead, Enzo argues that Dr. Berneman’s testimony concerning the meaning of the terms “commercial development, use and exploitation” violates the rules of contract

interpretation because Dr. Berneman supposedly admitted that he did not accord any different meaning to the terms “commercial use,” “commercial development,” and “commercial exploitation.” Enzo Br. at 11-12. Enzo then attempts to leverage this argument to preclude Dr. Berneman from testifying concerning the meaning of the research terms, asserting that, since the Agreement must be interpreted as a whole, opinions as to the meaning of the research terms cannot be given in the absence of an interpretation of the commercial terms. Enzo Br. at 15-16.

Enzo’s motion boils down to an assertion that Dr. Berneman was required to give three separate definitions for the terms “commercial use,” “commercial development,” and “commercial exploitation.” Enzo’s argument entirely misses the point of Dr. Berneman’s opinion with respect to these terms. In his expert report, Dr. Berneman discusses these three terms together because he is focusing on the meaning of the term “commercial” as it is used in connection with each of the words “use,” “development” and “exploitation.” For example, in paragraph 73 (a) of his report, Dr. Berneman states as follows:

In the life sciences industry, the customary and standard meaning of the terms Commercial Use, Commercial Exploitation, and Commercial Development of a research tool generally, and with respect to the Products at Issue, is employing the product in an activity directly tied to generating **a commercial return** (such as using the product for or in conjunction with a diagnostic test for which a customer would be charged a fee) or generating **a commercial return** by reselling the product.

Ex. 1, Berneman Report ¶ 73. This passage is clear and demonstrates that Dr. Berneman is focusing on the word “commercial” in concluding that the customary and industry meanings of the terms “commercial use,” “commercial development” or “commercial exploitation” in this context refer to employing the product in an activity directly tied to generating a commercial return, *i.e.*, a “commercial” activity. Since his focus is on the “commercial” aspect of the term, there was no reason to separately provide definitions for the words “use,” “development” or “exploitation.”

Similarly, in paragraph 73(b) of his report, Dr. Berneman distinguishes “applied research” from “commercial use,” “commercial development” or “commercial exploitation.”

There is no basis or support in industry customary and standard practice to conclude that “applied research” constitutes Commercial Use, Commercial Exploitation or Commercial Development. Using a research tool in a laboratory research activity that is not a clinical or therapeutic application; and where such use is not directly tied to generating *a commercial return*, would be understood by those in the life sciences industry as using such product for a research purpose. Such use would not be considered Commercial Use, Commercial Exploitation, or Commercial Development of the research tool.

Again, Dr. Berneman’s focus was not on the specific meanings of the words “use,” “development” or “exploitation.” He was simply stating his opinion that the customary and industry meanings of the terms “commercial use,” “commercial development” or “commercial exploitation” relate to using the product in an activity directly tied to generating a commercial return, *i.e.* “commercial” activity (as compared to “research” activity).

Dr. Berneman’s interpretation of the “commercial” terms follows well-recognized rules of contract interpretation under New York law. In particular, the canon of *noscitur a sociis* requires that “the meaning of a general term in a series [is to be] determined ‘by the company it keeps’”—*i.e.*, terms appearing in close proximity thereto. *In re Enron Creditors Recovery Corp.*, 380 B.R. 307, 322 (S.D.N.Y. 2008); *Harris v Allstate Ins. Co.*, 309 N.Y. 72, 76 (1955) (employing the “familiar principle of noscitur a sociis” to interpret contract). This doctrine clarifies when terms have similar or joint meanings. *See Dauphin v. Crownrbook ACC LLC*, No. 12-CV-2100 (ARR)(SMG), 2013 WL 1498363 (E.D.N.Y. Apr. 11, 2013) at *5 (applying *noscitur a sociis* to particular sentence in employment contract did not render preceding sentence superfluous, but “serve[d] to explain it with greater specificity”). Indeed, other witnesses interpreted these same terms in a similar manner, construing the terms as having a unified meaning relating to commercial activity within the context of the research restrictions. *See, e.g.*,

Ex. 5, 2014-01-24 Dimond Dep. Tr. at 77:11–78:13 (A: “We would have interpreted, because of the sentence about any commercial use, development or exploitation . . . [as] related to people not being able to take the product and resell it as their own product or make another product out of it to sell it or use it to manufacture a product.”).

Dr. Berneman did not testify or opine, as Enzo argues, that the terms “commercial use,” “commercial exploitation,” and “commercial development” are synonymous or “interchangeable.” Rather, consistent with his focus on the meaning of “commercial,” which is part of all three terms, he testified that the terms have *related* meanings and that they all within the general ambit of “commercial activity”:

Q: So, you consider those terms synonymous in terms of what you call the standard and customary usage?

A: I don’t believe I testified that I considered them synonymous. I consider them related.

A: We can parse more precise meaning to the terms. But they relate to the continuum of commercial activity.

See Ex. 2, Berneman Dep. Tr. 146:4–9; 183:10–14. In his deposition, Dr. Berneman also recognized that the terms were different insofar as there is a difference in meaning between use, development and exploitation, *see id.* at 146:11–24 (A: “To exploit, in this case, a research product in the marketplace, [is] to seek direct economic consideration for use, [and] selling . . . [D]evelopment . . . is to apply, to create, to move forward.”), and explained that because the terms “are used serially in the agreement at issue,” he used “them serially in discussing [his] report,” *id.* at 147, 183.

However, the simple fact is that there is no distinction between the various phrases “commercial development,” “commercial use,” and “commercial exploitation” that was relevant

to Dr. Berneman’s opinions at the time he submitted his report.² *See* Berneman Dep. Tr. at 108:12–109:9 (A: “I am suggesting that with respect to research products, the terms commercial use, commercial exploitation and commercial development would generally mean that . . . that research product[] directly []generat[ed] return.” (emphasis added)). It is in this context that Dr. Berneman testified that for purposes of his report, there was no need to draw out such a distinction between the terms. Lefton Decl. Ex. 4 at 145:12–147:8 (clarifying that he did not draw distinctions between the commercial terms “for the purposes of [his] analysis” and/or “for purposes of . . . [my] opinions in this matter”).

Indeed, Enzo’s insistence that Dr. Berneman should have separately opined on the meaning of each of those terms is completely contrary to the analysis performed by Enzo’s own expert, Dr. Azarani. In her expert report, Dr. Azarani opines that:

I do not believe the Distributorship Agreement’s research use only restrictions would permit applied research. The clear and express prohibitions on the use of the products sold under the Distributorship Agreement for diagnostic purposes or for commercial development or exploitation of the products, by definition, preclude applied research.

Ex. 3, Azarani Report at 9. Thus, Enzo’s own expert did not attempt to parse or explain the precise differences between “use,” “development,” and “exploitation” as Enzo argues Dr. Berneman should have.

For these reasons, the cases cited by Enzo to the effect that different terms in a contract should be given different meanings are simply beside the point. Contrary to Enzo’s argument, Dr. Berneman consistently interpreted the meaning of “commercial” as it appeared in each of the three terms at issue; he did not say that the three terms were synonymous. In sum, when Enzo’s

² Enzo filed two untimely supplemental reports after the date that Dr. Berneman completed and submitted his report. *See* March 3, 2014 Letter from R. Gunther to the Court (regarding motion to strike supplemental Bell report); March 3, 2014 Letter from R. Gunther to the Court (regarding motion to strike supplemental Azarani report).

distortions are set aside and Dr. Berneman’s actual opinion is analyzed, there is simply no basis to assert that he has violated any canon of contractual interpretation.

Finally, Enzo argues that the exclusion of Dr. Berneman’s opinion regarding the meaning of the “commercial” terms necessarily requires exclusion of his opinion on the “research” terms. Enzo Br. at 15–16. Because, as set forth above, there is no basis to exclude Dr. Berneman’s opinion on the commercial terms, the Court need not reach this issue. But even if Dr. Berneman was unable to testify about the commercial terms, Enzo’s assertion that his testimony with respect to both the “commercial” and “research” terms must rise and fall together, without analyzing the admissibility of Dr. Berneman’s testimony with respect to each term, is wholly without merit. Dr. Berneman’s opinions about “research” terms are set forth in a separate section of his expert report and stand on their own to assist the trier of fact in explaining the “research” terms in the Distributorship Agreement. In every case, only a limited number of contractual terms are at issue, such that the fact finder is always asked to focus on a discrete number of contractual terms or provisions. Dr. Berneman’s opinion concerning the research terms remains valid and admissible irrespective of whether he provides an opinion as to the “commercial” terms.

III. ENZO’S MOTION TO PRECLUDE TESTIMONY REGARDING THE TERM “COVERED BY” SHOULD BE DENIED AS MOOT

Enzo has also moved to preclude Dr. Berneman’s testimony regarding the meaning of the phrase “covered by one or more claims of an Enzo patent” in the definition of the term PRODUCT on the grounds that (1) it is not proper rebuttal testimony and (2) it is unreliable under FRE 702. Enzo Br. at 3–10. At various points in this and the related cases, Enzo has intimated that the phrase means something other than infringement of one or more claims of an Enzo patent. For example, in its litigation with Roche, Enzo suggested that this phrase should be

interpreted to mean that a “reasonable business person” would understand that “the product and patent claim in question include the same technology.” Ex. 6, December 6, 2013 Joint Letter to the Court at 5 (04-cv-4046). Because several passages in Enzo’s expert reports could have been construed as presenting opinion testimony as to such a meaning, Dr. Berneman offered a responsive opinion in his report.

However, in its *Daubert* motion, Enzo has made clear that it has not and will not offer any opinion “on the meaning, custom or usage of ‘covered by the claims of an ENZO PATENT.’” Enzo Br. at 4. In fact, Enzo goes on to say that “Dr. Sherman never opined that a showing lesser than [patent] infringement . . . was intended by that term.” *Id.*

In view of these concessions by Enzo, Dr. Berneman will not be offered at trial to testify concerning any opinions with respect to the term “covered by.” Accordingly, Enzo’s motion should be denied as moot.

CONCLUSION

For the foregoing reasons, PerkinElmer respectfully requests that the Court deny Enzo’s motion to exclude testimony or opinions by Dr. Louis Berneman.

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